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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,746	06/29/2001	Ronald J. Pettis	7767-173562	4733

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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
BOUCHELLE, LAURA A	
ART UNIT	**PAPER NUMBER**
3763	

MAIL DATE	DELIVERY MODE
01/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/893,746	PETTIS ET AL.	
	Examiner	Art Unit	
	Laura A. Bouchelle	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *119-121,127-136 and 139-142* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *119-121,127-136 and 139-142* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/8/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 119-121, 127, 129-131, 132-134, 136, 139-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (US 5848991) in view of D'Antonio et al (US 60567116) in further view of Prausnitz et al (US 6611707). Gross discloses a method of delivering drugs, including heparin, intradermally (Col. 3, lines 40-41) using a single needle with an outlet at a depth of 250 um - 2mm in a controlled manner based on needle diameter (Col. 4, lines 10-35). Gross discloses that the delivery can be infusion, pulsatile, or intermittent doses (Col. 4, lines 49-53) and that the dose rate can be varied as per the individual or drug type delivered needs (Col. 4, lines 55-57; Col. 5, lines 26-30; Col. 8, lines 13-15). Upon delivering medication to the intradermal compartment, the physiology of this location causes the improved systemic absorption as compared to bolus subcutaneous injections (Col. 3, lines 38-44). This limitation suggests that there is improved systemic absorption. A bevel is considered to be analogous to an opening in the side of the needle. Gross does not explicitly state that the delivery is by bolus administration, however, in view of the disclosure in Gross that delivery rates can be varied according to the patient's needs (see cite above) it would be obvious to one of ordinary skill in the art to deliver the disclosed drugs via bolus administration. One of ordinary skill in the art would recognize that drug delivery can be bolus administration or infusion and that various drugs and patient conditions suggest different rates. In view of the different delivery

rates that the prior art device can perform, one of ordinary skill would find obvious that the Gross disclosure, taken as a whole, suggests bolus administration as well as infusion rates.

3. Gross does not expressly disclose that the intradermal delivery achieves improved systemic absorption relative to absorption upon injecting subcutaneously. D'Antonio (Col. 3, lines 27-28; Col. 29, lines 3-26) suggests that medication delivered intradermally results in improved systemic absorption. D'Antonio teaches ID injections for growth hormones, vaccines, sera, vitamins, and nutrients. D'Antonio discloses that intradermal injection testing shows a better absorption than subcutaneous injection as evidenced by tests showing that ID is more potent than subcutaneous injections. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of D'Antonio in the method of Gross in order to achieve a therapeutic result using less drug. The cost savings and ability to effectively deliver scarce drugs to a larger number of people would motivate one of ordinary skill in the art to modify the method of Gross with the teachings of D'Antonio.

4. Claims 119, 132 further differ from Gross in calling for the needle to have an exposed height from 0 mm to about 1 mm. Claims 129, 141 call for an exposed height of the needle outlet to be 0 mm. Prausnitz teaches the use of needles with zero exposed height to deliver drugs into the skin (Col. 3, lines 27-38). It would have been obvious to one of ordinary skill in the art at the time of invention to use the teachings of Prausnitz in the method of Gross in order to provide a known flow dynamic as desired from the end of the delivery needle. The zero exposed height needle as disclosed in Prausnitz is known to provide a substantially longitudinally directed flow as opposed to a more pronounced radially directed flow component as found in beveled

needles when liquid exits the needle opening. One of ordinary skill in the art would know to select a particular exposed height needle dependent upon the desired flow delivery.

5. The use of nanoparticles are considered as equivalent to the disclosed use of microparticles in the prior art, and obvious to give improved absorption, particularly in consideration that the nanoparticles are even smaller than the microparticles. Additionally, in view of the large number and classes of drugs listed by Gross for delivery by the disclosed method, the use of dopamine receptor agonist would have been obvious to one of ordinary skill in the art because it is recognized as another similarly administered drug, intradermally or subcutaneously (See Gross, Col. 6, line 41 - Col. 7, line 20). It would be obvious to one of ordinary skill in the art to apply the prior art method to additional drugs in view of the teachings of broad applicability to different drugs.

6. Claims 128, 135, 142 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of D'Antonio as applied to claims 119, 132 above, and further in view of Ganderton et al. (US 3,8 14,097). Gross discloses the claimed method except for using an array of needles. Ganderton discloses injecting a substance through multiple needles (Col. 1, lines 9-40; fig. 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Ganderton in the method of Gross and D'Antonio in order to facilitate the distribution of larger quantities of delivered drug to a patient.

Response to Arguments

7. Applicant's arguments filed 1/30/07 have been fully considered but they are not persuasive.

8. Applicant argues that Gross fails to teach the outlet of the needle located within the intradermal space. Gross clearly discloses an intradermal drug delivery device which delivers drug to the intradermal space.

9. Applicant further discloses that the combination of Gross and D'Antonio is improper. D'Antonio is only used as a teaching reference to teach that an injection into the intradermal space is known to improve intradermal absorption. It is inconsequential whether the reference discloses the delivery of a vaccine or a drug (furthermore, the examiner argues that a vaccine is a drug).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
Art Unit 3763